

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

In vivo effect of 5 French bipolar and monopolar electrosurgical probes on the porcine bladder

R. D. Tucker, E. V. Kramolowsky, and C. E. Platz

Department of Pathology and Urology, University of Iowa Hospitals and Clinics, Iowa City, IA, USA

Accepted: October 10, 1989

Summary. Previous in vitro studies have indicated bipolar electrosurgical probes would electrodesiccate tissue in a normal saline solution. This study applies similar sized monopolar and bipolar electrosurgical probes to porcine bladder in order to compare each probe's effect in vivo. The power delivered by each probe was calculated; the width and depth of the porcine bladder damage was measured and the volume of the damage calculated. The animals were sacrificed at 24, 48 and 96 h post-procedure so that the amount of tissue destruction could be quantitated relative to the bladder's natural tissue reaction. The data shows the power (watts) delivered by the monopolar probe to be approximately six times that of the bipolar probe. Likewise, the area of bladder wall damage was larger with monopolar at all time periods sampled and showed significant differences at 24 and 48 h. These studies indicate that in viable bladder, tissue bipolar probes will electrodesiccate at a lower power and with less short-term tissue damage.

Electrosurgical instruments and techniques have become common in the modern operating room. Radio frequency (RF) current can be applied either in a monopolar (the current travelling from active electrode thru the tissue to a distant return electrode or ground pad) or bipolar (the current travelling from one part of the active electrode through tissue to another part of the active electrode) mode. For over the past 50 years, urologists have applied radio frequency monopolar current to endoscopic procedures in the genitourinary tract, especially the urethra and prostate [1]. Since monopolar electrodes function poorly in normal saline, early procedures were performed in sterile water and later in glycine solutions. The transmission of the radio frequency current and their associated low frequency currents [8] through the patient has been associated with troublesome adductor muscle contractions complicating

urologic procedures as well as ventricular fibrillation [3, 6].

Advances in technology now allow the manufacture of bipolar electrodes in similar size and shape as monopolar probes. Testing of the bipolar electrode has shown that it will electrodesiccate tissue when bathed in normal saline solution unlike similar monopolar electrodes [7, 9]. This probe has been effective when applied to the uroepithelium in dogs [5].

Based on our previous in vitro studies, we now present an in vivo comparison of similar monopolar and bipolar electrodes on viable porcine bladders in order to determine their effect on living epithelium.

Materials and methods

Nine female pigs, weighing between 100-140 lbs, were given general endotracheal anesthesia in the supine position. They were prepped and draped for sterile surgery. In each animal, a midline lower abdominal incision was performed. While remaining extraperitoneal, the bladder was identified and opened longitudinally on its anterior surface. The trigone was visualized and used for orientation of the electrode applications. The electrodes were held in a specially constructed test jig such that only a constant 2.5 mm of the electrode tip could be placed in contact with the bladder mucosa. This method of electrode application produced consistent tissue-electrode contact area. Each electrode was applied to viable intact, non-bleeding bladder mucosa. A solution of either normal saline (bipolar electrode) or sterile water (monopolar electrode) at room temperature was infused at 5 cc/s over the electrode and the bladder mucosa such that both were completely submerged during current application. The RF current was applied for exactly 2 s by a timing circuit connected to the electrosurgical generator foot pedal input. Upon completion of electrode applications and mapping of the bladder sites, the bladder was irrigated with normal saline, emptied and closed in two layers with 3-0 chromic cat gut suture. The abdominal wound was closed without drainage. During electrode application, care was taken to choose sites away from the bladder incision so that inflammation and mucosal swelling from the bladder closure would not involve the burn sites.

All animals survived the anesthesia and surgery and were sacrificed at 24, 48 or 96 h intervals. The bladders were removed in total, opened anteriorly and superiorly, pinned flat to prevent

ETHI 100323

Table 1. Power, volume, diameter and depth (\pm S. E.) for burns on porcine bladders

	N	Power (watts)	Volume (mm ³)	Diameter (mm)	Depth (mm)
24 h					
Bipolar	16	10.4 \pm 0.4	1.23 \pm 0.18	2.40 \pm 0.20	0.47 \pm 0.07
Monopolar	15	63.4 \pm 3.2	9.87 \pm 2.31	4.16 \pm 0.36	0.92 \pm 0.15
P-value			< 0.0005	< 0.0005	0.005
48 h					
Bipolar	8	10.3 \pm 0.7	1.82 \pm 0.47	2.58 \pm 0.34	0.53 \pm 0.10
Monopolar	13	64.1 \pm 2.2	6.73 \pm 0.72	4.28 \pm 0.20	0.85 \pm 0.07
P-Value			< 0.0005	< 0.0005	0.008
96 h					
Bipolar	7	10.4 \pm 0.4	0.14 \pm 0.05	0.77 \pm 0.14	0.25 \pm 0.09
Monopolar	9	69.0 \pm 7.5	0.92 \pm 0.37	1.75 \pm 0.25	0.46 \pm 0.08
P-value			0.04	0.005	0.06

Table 2. P-values for comparisons of burns between sacrifice times

	24 h vs 48 h		48 h vs 96 h	
	Bipolar	Monopolar	Bipolar	Monopolar
Volume	0.10	> 0.25	0.003	0.007
Diameter	> 0.25	> 0.25	0.0005	0.009
Depth	> 0.25	> 0.25	0.02	0.03

shrinkage, and fixed for at least 24 h in 10% buffered formalin. Burns were identified, coded alphanumerically, and located on a map correlating the electrode positions and burn sites. A single transmural block of each burn was taken with the burn centrally positioned in the block. Tissue blocks were processed to paraffin, embedded, and three duplicate step sections taken of each block at three levels. One of each duplicate was stained with hematoxylin and eosin (H&E), the other used for stains particularly trichrome as needed. If the expected burn was not identified in the initial slides, three additional levels were cut. The slides were examined microscopically and measurements of the maximum width, thickness, and depth of the defect were taken for each burn using an ocular micrometer. The burn surface diameter was measured as the distance from edge of the normal tissue on one side of the burn to the edge on the opposite side. The burn depth was obtained from an imaginary line across this space to the deepest point of the burn. From the histology slides, measurements of depth and width of burns, and observations regarding extent of edema and inflammation were made in a blinded fashion. All slides were examined by one observer (CEP) who did not know the experimental conditions.

The burn was modelled as a spherical cap or truncated hemisphere and the estimated volume of the burn was calculated from the surface diameter (D) and depth(d) measurements by [8]:

$$V = (0.67R^3 - R^2X + 0.33X^3)$$

$$\text{where } R = (D^2/8d) + (d/2) \text{ and } X = R - d$$

The probes were 5 FR and manufactured by ACMI. The bipolar probe was the commercially available ACMI BICAP probe. The bipolar probe tip consists of a 6 mm long ceramic shaft with a rounded end. The shaft has four metallic strips 1 mm wide equally spaced around the shaft. Two of the opposing strips are attached

together across the crown of the tip to form a single electrode. The remaining two strips are attached internally in the catheter and constitute the remaining half of the bipolar electrode. The monopolar probe utilized the bipolar ACMI BICAP probe tip with the bipolar conductors connected together by a single wire, thus, creating a custom monopolar electrode with a bipolar tip.

Initially, the power delivered into the tissue was determined by a circuit which converted the RF generator voltage and current into direct current (DC) voltages and the values recorded vs. time on a strip chart recorder; the power was then calculated by multiplying voltage times current [10]. Later, a multiplying chip was added so the power could also be directly recorded on the strip chart. This measuring system allows matching of the burn site histology with the power delivered to the site for each electrode.

The statistical differences between burn volumes, depth and diameter for the three time periods were calculated by standard student's-t-test.

Results

The power output of each electrode application was measured and was approximately 10 watts for bipolar and 60-75 watts for monopolar. The power output variation was much greater in the monopolar system. The diameter and depth of tissue damage was significantly less with the bipolar electrode compared to monopolar, and likewise, a significant difference in the volume of the burn was present. The differences were more obvious at 24 and 48 h and less at 96 h (see Table 1).

Comparison of the differences between sacrifice times and their related volume, depth and diameter showed the largest differences between monopolar and bipolar occurred 24-48 h, and at 96 h the difference had decreased (see Table 2).

From examination of the histologic sections of treated tissue, differences in depth and extent of burns and degree of inflammation were evident, however, and it was clear that some of the burns extended in a narrowly linear and often diagonal fashion through the wall of the bladder. After these observations were recorded and the statistical analysis performed on the numerical data, the slides were

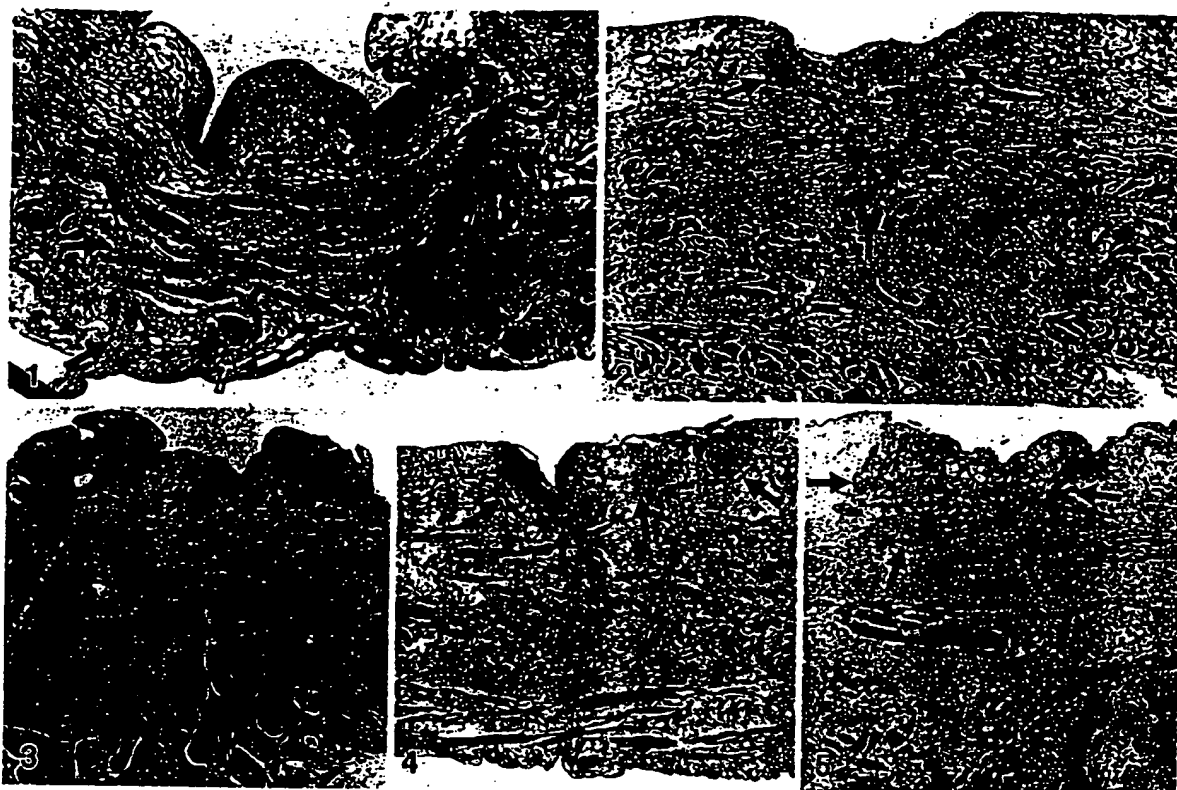


Fig. 1. Monopolar burn, 24 h post surgery group. The burn displays mucosal ulceration and transmural necrosis (arrows) of the muscularis and a large thrombus (open arrow)

Fig. 2. Bipolar burn, 24 h post surgery group. The burn shows an area of mucosal ulceration and a separate area (to the right of the ulcer) of hemorrhage; these two areas correspond to two of electrode traces on the bipolar electrode. There is minimal necrosis (arrows) to smooth muscle and connective tissue

Fig. 3. Monopolar burn, 48 h post-surgery. The burn shows necrosis (solid arrows) which extends to smooth muscle. There is an area of prominent vessel coagulation (open arrow)

Fig. 4. Bipolar burn 48 h post-surgery. The burn shows little mucosal ulceration with necrosis (arrows) extending to some smooth muscles

Fig. 5. Monopolar burn, 96 h post-surgery. The burn shows necrosis (arrows) with surrounding inflammation and edema. There is re-epithelialization on the mucosal surface

sorted by time between burn and sacrifice, and type of electrode burn. These were then re-reviewed in an attempt to determine whether there was a pattern to either the bipolar or monopolar electrode and to ascertain the inflammatory and reparative changes over time. The only difference which was detected, other than size and depth of the burn which might separate the monopolar from bipolar electrode, was that the burns which extended in a linear fashion through the wall were from the monopolar electrode.

The changes within the first 24 h were largely those of coagulation necrosis and surrounding edema. Figures 1 and 2 are representative of 24 h post monopolar and bipolar electrode burns. By 48 h, a polymorphonuclear infiltrate was evident with a marked increase in the amount of edema. The localization of the extent of necrosis was usually more easily defined by 48 h and isolated focal segmental vascular necrosis was occasionally noted at a distance from the one of primary necrosis in some cases. Figures 3 and 4 show 48 h post monopolar and bipolar electrode burns. The degree of inflammatory infiltrate was varied and appeared to be related to the animal rather than to the type of burn, some animals showing a very marked neutrophilic response, others showing a slight to moderate one, the degree of response being similar from one burn to the other with a given animal. Occasional small vessels around the burns showed a slight endothelial proliferation at 48 h, but by 96 h this became more marked. In general, 96 h burns showed evidence of repair with vascular proliferation and fibroblast infiltration of the margins of necrotic areas, as well as re-epithelialization of the surface of the necrotic areas in some animals (Fig. 5).

Discussion

This study has attempted to evaluate the effects of similar monopolar and bipolar electrodes on live animal bladder

and to determine changes which occur due to live tissue reaction.

We had elected to use normal saline for the bipolar electrode and sterile water for monopolar electrode because these were the fluids in which we found optimal electrode function. The conductivity of tissue is slightly less than saline while sterile water has a high resistance. A 1.5% glycine solution has slightly less resistance than water.

The power delivered to the tissue by the monopolar vs. the bipolar electrode was dramatically different and is primarily due to the different resistance seen by each electrode. The bipolar electrode/tissue is a very low resistance system, while the monopolar/tissue/return electrode (ground electrode) is a much higher resistance system. As a result, it would be impossible to simply "turn down" the power on the monopolar system to achieve lower power and less tissue destruction as in the bipolar system. In fact, the monopolar electrode with the sterile water bathing solution could not consistently produce burns at lower power settings.

The diameter and depth of penetration of the tissue damage varied significantly between electrodes and in all cases it penetrated the uroepithelium with less volume of damage noted in the bipolar system. The tissue volume seemed to not change between 24 to 48 h, but at 96 h the volume of tissue burn for the same amount of power applied was much less in both systems. Also, at 96 h, the amount of tissue damage between the two electrodes was less and not highly significant. These changes are related to the healing process. Microscopic analysis confirmed this by showing more endothelial and vascular proliferation, fibroblast infiltration and re-epithelization at 96 h than at the early times.

Others have compared the effect of bipolar electro-surgery on the bladder to that of Neodymium-Yag laser, as both exhibit decreased depth of penetration of necrosis and are more controlled than monopolar electro-surgery [4]. Indeed we have found a significant difference in depth of penetration between monopolar and bipolar in the first 48 h which decreases at 96 h.

The possible clinical advantages of bipolar electro-surgery over monopolar electro-surgery include: increased patient safety by elimination of the return electrode (ground pad), minimizing the amount of unwanted tissue damage as the current is constrained to a small volume, and the reduction of generator power output, thereby, reducing nerve and muscle stimulation as well as reducing electrical interference. Theoretically, fulguration of superficial bladder lesions with the bipolar electrode would be less likely to result in perforations as is the case with the Nd:YAG laser. Both the laser and bipolar electro-surgical probes are flexible and of sufficiently small caliber to allow passage through almost all urologic instruments. The bipolar system is simpler to set up and less costly than

a laser system, which may more readily facilitate bipolar system use in an office setting. Neither the Nd:YAG laser nor the bipolar electro-surgical probe is effective in cutting tissue which is a limitation when considering its use for transurethral prostatectomies. However, further technological advances may allow cutting of tissue using bipolar current which would allow the urologic surgeon to perform transurethral prostatectomies in a normal saline solution.

These animal studies show that bipolar electro-surgery is effective on viable urogenital tract in a normal saline irrigation and at much lower power levels than normally applied with monopolar electrodes. The bipolar electrode also displayed less depth and volume of tissue destruction. These properties of bipolar electro-surgery may offer an advantage for the urologic endoscopist.

References

1. Collings CW (1932) Transurethral electro-surgery for the relief of prostatic obstruction. *J Urol* 28:529
2. Hoyt RH, Huang SK, Marcus FI, Odell RS (1986) Factors influencing trans-catheter radio frequency ablation of the myocardium. *J Appl Cardiol* 1:469
3. Hungerbuhler RF, Swope JP, Reves JG (1974) Ventricular fibrillation associated with use of electro-surgery. *JAMA* 230:432
4. Kriegsmair M, Persel J, Hofstetter AG, Fastenmeier K, Rothenberger KH, Keiditsch E, Boemers TML (1987) Regulated high frequency diathermy for bipolar electrocoagulation - a new method for the treatment of carcinoma of the bladder. *Urol Res* 15:251
5. McDermott TE, Fitzpatrick JM, Suatengco D, Grossman BH (1987) A new probe for bipolar diathermy for upper urothelial tract tumors. *J Urol* 137:235A
6. Prentiss RJ, Harvey GW, Bethard WF, Boatwright DE, Rennington RD (1965) Massive adductor muscle contraction in transurethral surgery: cause and prevention development of new electrical circuitry. *J Urol* 93:264
7. Ramsay JW, Shepherd NA, Butler M, Gosling PT, Miller RA, Wallace DM, Whitfield HN (1985) A comparison of bipolar and monopolar diathermy probes in experimental animals. *Urol Res* 13:99
8. Tucker RD, Schmitt OH, Sievert CE, Silvis SE (1984) Demodulated low frequency currents from electro-surgical procedures. *Surg Gynecol Obstet* 159:39
9. Tucker RD, Kramolowsky EV, Platz CE (1988) Comparison of urologic application of bipolar versus monopolar five french electro-surgical probes. *J Urol* 141:662
10. Tucker RD, Stasz PS, Kramolowsky EV, Platz CE (1989) A simple and inexpensive method for measuring electro-surgical variables. *Biomed Instrum Tech* 23:54

Robert D. Tucker, PhD, MD
Department of Pathology
27 Med Labs
University of Iowa Hospitals and Clinics
Iowa City, Iowa 52242
USA